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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,233	08/08/2001	Wilbur L. Eidson	01-4236	3429

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EXAMINER

THISSELL, JEREMY

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/27/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/924,233

Applicant(s)

EIDSON ET AL.

Examiner

Jeremy T. Thissell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 8,12,17,20,27-29,31-33 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-11,13-16,18,19,21-26,30 and 34-42 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Information Disclosure Statement***

It appears that applicant has filed two information disclosure statements, however only the later of the two was found in the case file. If indeed Applicant has filed an additional IDS (on 9 October 2001), the Examiner requests that a copy of the IDS be sent with Applicant's response, along with copies of any foreign patents or non-patent literature cited thereon.

### ***Election/Restrictions***

Claims 8, 12, 17, 20, 27-29, 31-33, and 43 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Applicant's election with traverse of the species restriction requirement in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the examiner has not set forth the differences between the species and why it would be burdensome to examiner all of them. The species are clearly different in that one is for injecting one medicament at a time, and the other is for injecting two. Injection of multiple medicaments requires structure (e.g. multiple needles or a mixing chamber as in applicant's sub-species) that need not even be considered when examining an apparatus for injection of a single medicament. Thus, the types of devices are

substantially different. The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 18, 19, 21-25, 34-37, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "said proximal surface" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 and other claims also seem to incorrectly use the word "proximal" when referring to the distal surface of the injector. It is conventional to refer to medical instruments with respect to the USER not the patient. Therefore, the surface of the injector where the needle is attached is the *distal* surface because it is *distal* with respect to the *user* (i.e. facing away from the healthcare provider).

Claims 18, 19, and 21 refer to the device as a "first," "second," and "fourth" hand-held injection device, respectively. This differentiation between embodiments is unnecessary. Each of these claims should simply refer to the device as "the hand-held injection device."

In claim 23, an "Amp" electrical connector is a *brand* of connector. Not only is it impermissible to use a trademark or trade name in the claims, but Amp, Inc. makes

many different kinds of connectors, and thus the limitation "amp electrical connector" is not specific to any specific structure.

Claim 34 recites the limitation "said gun" in section a) of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 42 recites the limitation "said control unit" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 38 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lemelson (US 5,993,378).

See columns 24-26, particularly col. 24, lines 46-47, which teach that the device can include a needle attached to the end of the device instead of a catheter.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3763

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson '378 in view of Niehoff (US 5,928,197).

Lemelson teaches all the claimed subject matter except for an emergency stop button on the dorsal surface. Niehoff teaches an injector having an emergency stop button (45) on the dorsal surface. It is well-known in the art of injectors to have an emergency stop button as a safety feature, and Niehoff teaches the desirability of having it on the dorsal surface, in plain view, and clear access. It would have been obvious to one of ordinary skill in the art to include the emergency stop button of Niehoff on the device of Lemelson, to allow the user to stop the injection immediately in the event of an emergency.

Claims 3 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson '378 in view of Denance (US 5,034,003).

Lemelson teaches all the claimed subject matter except for a safety interlock. Denance teaches a safety interlock (40) such that it must be depressed in order to allow the fluid to be injected (see col. 5, line 55—col. 6, line 18). Again, safety features such as these are well-known in the art of medical injectors, and would have been obvious to one of ordinary skill in the art to include on the device of Lemelson to prevent undesired injections.

Claims 4, 5, 9, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson '378 in view of Kobayashi (US 4,469,481).

Lemelson teaches all the claimed subject matter except for a dose limiter controlled by a photo-optic sensor. Kobayashi teaches a medical infusion device having an optic sensor for controlling the unit dose (see element 68 and col. 7). Dosing and dose control mechanisms are widely-known in the art of medical injections. Inclusion of the sensor system of Kobayashi on the device of Lemelson would have been obvious.

Claims 6, 10, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson and Kobayashi (US 4,469,481) as applied to claims 5 and 9, and further in view of Denance (US 5,034,003).

Lemelson as modified by Kobayashi teaches all the claimed subject matter except for a light indicating that the injection is taking place. Denance teaches such an indicator light. (col. 4, lines 57-58) Indicators for the status of the injection are well-known in the art of medical injectors and it would have been obvious to include the injection-in-progress light of Denance on the device of Lemelson in order to advise the user of the injection taking place.

With regard to claim 13, see the discussion above about the safety interlock of Denance.

Claims 7, 11, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson, Kobayashi, and Denance as applied to claims 6 and 10 above, and further in view of Kriesel et al (US 5,840,071).

Lemelson as modified by Kobayashi and Denance teaches all the claimed subject matter except for an indicator for when the injection fluid is low. Kobayashi teaches that there is an alarm to change the reservoir, but that it simply goes off daily at a specified time. However, Kriesel teaches an alarm indicating with the fluid is low (col. 3, lines 49-50). It would have been obvious to include the alarm of Kriesel on the device of Lemelson in order to alert the user that the injection fluid will run out if they do not provide a new supply.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson in view of Wallach (US 3,949,746).

Lemelson teaches all the claimed subject matter except for a marking tip. Wallach teaches a marking tip (28) so as to identify those patients who have been given a particular injection. It would have been obvious to include a marking means on the device of Lemelson so as to identify patients who have had an injection, of say, a vaccine.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson and Wallach as applied to claim 19 and further in view of Exodax 20/50 owners manual (1993), hereinafter referred to as "Exodax."



Lemelson as modified by Wallach teaches all the claimed subject matter except for quick connect fittings. Exodax teaches a fluid dispenser having quick connect fittings for the fluid hoses. (page 19, diagram parts list, item #22) Quick connect or quick release fittings or couplings are well-known and desirable for their rapid connection and disconnection capabilities in both fluid couplings and electrical couplings. It would have been obvious to provide the device of Lemelson with quick connect fittings such as those in Exodax, so as to allow timely assembly and disassembly, during use or cleaning of the device.

It should be noted that an "Amp" electrical connector is a brand of connector, rather than a specific type of connector. Without further limitation of the connector structure, this limitation is met by the non-specific connectors of the prior art cited.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson, Wallach, and Exodax as applied to claim 23 above, and further in view of Kobayashi (US 4,469,481).

Lemelson as modified by Wallach and Exodax teaches all the claimed subject matter except for controlling the dose with the use of a photo-optic sensor. See discussion above of the combination of Kobayashi with Lemelson.

Claims 26 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson in view of Reimels (US 5,580,347).

Lemelson teaches all the claimed subject matter except for the pump being a self-priming peristaltic pump and that the pump has a cleaning mode. Reimels teaches a surgical injector with a self-priming peristaltic pump. (col. 7, line 65; col. 8, lines 20-35) Peristaltic pumps are universally known for their use in medical infusion and for most procedures they must be primed because it is dangerous to inject air into the patient's body. Because of this standard procedure, it is well-known that many peristaltic pumps automatically "self-prime" as does Reimels. It would have been obvious to use the self-priming peristaltic pump of Reimels as the pump in the Lemelson system, so as to simplify and automate the priming step, a modification well within the level of ordinary skill in the art.

Further, the prime mode appears to meet the limitation of applicant's claimed "clean mode" since it flushes the system in a similar manner. Further, the device operates in a forward and in a backward flow direction, either of which would effectively clean the device.

#### ***Allowable Subject Matter***

Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 34-37 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Claims 18 and 21 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art does not teach a pump injector having a headlamp on the housing for illuminating the injection site. The prior art teaches endoscopic devices where the light is shone through the endoscope down to the tip for viewing of surgical sites deep within the body. The prior art also teaches devices with lamps for photodynamic therapy. The prior art further teaches alignment light beams for exact placement of injection needles, wherein the lamp is not attached to the housing. But the prior art does not teach a lamp on the distal end of the housing simply for illuminating the injection site.

Claims 34-37 contain the same subject matter allowed in the parent application, that the pistol is made with a housing and handle that pivot relative to one another.

***Prior Art***

For the convenience of all parties, a list of all the references used in this office action is provided below.

Lemelson (US 5,993,378)

Niehoff (US 5,928,197)

Denance (US 5,034,003)

Kobayashi (US 4,469,481)

Kriesel et al (US 5,840,071)

Wallach (US 3,949,746)

Exodax 20/50 owners manual (1993)

Reimels (US 5,580,347)

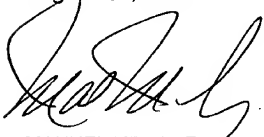
### ***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt  
August 23, 2003



MANUEL MENDEZ  
PRIMARY EXAMINER